REMARKS

Favorable reconsideration is respectfully requested in view of the above amendments and the following remarks. Following the amendments, claims 1-3 and 5-20 are pending and under consideration, with claim 1 being in independent format.

Figure 3 has been amended as requested by the Examiner to correct an error in the reference characters. Specifically, one occurrence of the number 113 has been replaced with 103. Support for this amendment may be found, for example, in the last paragraph on page 18 of the parent PCT application (paragraph 0077 of the published US application).

Claim 4 has been cancelled from the application. Independent claim 1 has been amended to include subject matter previously recited in claim 4 and to correct minor typographical errors. Specifically, claim 1 has been amended to recite a sample testing device including a signal processing means that includes a timer which, upon activation, sets a pre-determined time period for a sample to reach the detection arrangement, and wherein detection of the presence or absence of sample is made within the pre-determined time period such that presence of the sample produces a negative result and absence of the sample produces a positive result. Support for this amendment may be found, for example, in now cancelled claim 4, in the paragraph bridging pages 7 and 8 of the parent published PCT patent application, and in the last paragraph on page 12 of the parent published PCT application (paragraphs 0026 and 0045, respectively, of the published US application).

Claims 18-20 have been added. Support for claims 18 and 19, which depend upon claim 17, may be found for example in paragraph 0024 of the published US application as filed. Support for claim 20, which depends upon claim 1, may be found for example in cancelled claim 4,

It is urged that support for all the above amendments may be found throughout the specification as originally filed and that none of the amendments constitute new matter or raise new issues for consideration.

Drawing Objections

The Examiner noted that the reference character "113" was used to designate two different elements in the figures. This error has been corrected.

Specification Objections

The Examiner objected to the specification as lacking the required subtitles. However, applicants respectfully note that subtitles were added to the specification in the Preliminary Amendment filed with the application on September 16, 2005. Withdrawal of this objection is therefore requested.

Claim Objections

Claim 1 was objected to due to the presence of "a" in section (a). This has been corrected.

Claim rejections under 35 USC §102

Claims 1-4, 7, 8, 12 and 17 stand rejected under 35 USC §102(b) as being taught by Minter et al. (WO 00/33063). This rejection is respectfully traversed in view of the above amendments and the following remarks.

The present claims are directed to a sample testing device for detecting the presence or absence of a component of interest in a liquid sample. The testing device comprises at least one test capillary tube that includes an agglutination reagent system capable of causing agglutination with the component of interest, and a detection arrangement that detects the presence of liquid at a downstream region of the test capillary. As detailed in paragraph 0024 of the published application, if agglutination occurs (i.e. if the component is present in the liquid sample), the flow of liquid along the test capillary will either stop such that the liquid does not reach the detection arrangement, or will be slowed down such that the liquid does not reach the detection arrangement within a predetermined time interval. Accordingly, as recited in amended independent claim 1, a negative result is produced if the component is present in the sample, and a positive result is produced if the component is absent from the sample.

In contrast, Minter et al. do not disclose an agglutination assay. Rather Minter et al. describe detection of an analyte in a liquid sample using an electrochemical sensor that includes a reagent, such as an antibody, specific for the analyte. The analyte, if present, binds to an enzyme-labeled analyte-specific antibody provided in a first region of an assay track. As described on pages 10 and 11 of Minter et al., as the liquid sample moves down the track, the analyte-antibody complex binds a further antibody in a second region of the track to form an antibody-analyte-antibody sandwich. The liquid sample continues to move down the track until it reaches a third region of the track, where the enzyme label of the first antibody catalyzes a reaction, resulting in a detectable signal. Thus, with the device of Minter et al. a positive result is only obtained if the analyte is present in the sample. Minter et al. employ a standard antibody-analyte binding reaction, not agglutination.

Minter et al. do not teach or suggest the use of an agglutination reagent as recited in independent claim 1, not do they teach or suggest a test device wherein the presence of a component of interest in a test sample results in a negative results and the absence of the component results in a positive result, as clearly recited in amended claim 1. Furthermore, Minter et al. do not teach or suggest a device including a detection arrangement and a timer which, upon activation, sets a pre-determined time period for the test sample to reach the detection arrangement and wherein detection of the presence or absence of the liquid sample is made within the pre-determined time period, also as recited in amended independent claim 1.

Applicants respectfully submit that none of the presently pending claims are either anticipated or rendered obvious by the disclosure of Minter et al., and that the rejection of claims 1-4, 7, 8, 12 and 17 under 35 USC §102(b) may thus be properly withdrawn.

Claim rejections under 35 USC §103

Claims 5, 6, 9 and 10 stand rejected under 35 USC §103(a) as being unpatentable over Minter et al. (WO 00/33063) in view of Pronovost et al. (US 5,786,220). This rejection is respectfully traversed.

The teachings of Minter et al. are discussed above.

Pronovost et al. disclose a standard membrane lateral flow test, specifically for the measurement of hCG and progesterone in order to detect abnormal pregnancy. Example 1 of the reference describes a standard sandwich assay, in which an immobilized anti-hCG antibody is provided in a capture zone in order to capture analyte bound to blue latex beads. In this way, binding of the blue latex beads to the capture zone indicates presence of the analyte. As the anti-hCG antibodies are immobilized in a capture zone, they are unable to mediate agglutination of the blue latex beads and/or the analyte. Therefore, the reagents are not "agglutination reagents" as recited in independent claim 1. Nor do Pronovost et al. teach or suggest a test device wherein the presence of a component of interest in a test sample results in a negative result and the absence of the component results in a positive result, as recited in independent claim 1. Thus the teachings of Pronovost et al. do not overcome the deficiencies of Minter et al. discussed above.

It is submitted that neither Minter et al. nor Pronovost et al., taken either singly or in combination, would have rendered the presently claimed invention obvious to one of skill in the art at the time the invention was made, and that this rejection of claims 5, 6, 9 and 10 under 35 USC §103(a) may thus be properly withdrawn.

Claim 11 stands rejected under 35 USC §103(a) as being unpatentable over Minter et al. (WO 00/33063) in view of Pronovost et al. (US 5,786,220), and further in view of Parsons et al. (EP 0321736). The Examiner states that "Minter et al. teaches downstream regions of the test capillary have at least one aperture and the detection arrangement is provided beneath said aperture", but does not provide any information regarding the perceived relevance of Parsons et al. Clarification of this rejection is respectfully requested.

Applicants note that Parsons et al. do not teach or suggest an integrated testing device comprising a power source, a detection arrangement, display means and signal processing means, wherein the signal processing means includes a timer and wherein detection of the presence or absence of a liquid sample at the detection arrangement is made within the pre-determined time period, as recited in amended independent claim 1. It is submitted that neither Minter et al., Pronovost et al. nor Parsons et al. anticipate or render obvious the presently claimed subject matter and that this rejection of claim 11 may be properly withdrawn.

Claims 13, 14 and 16 stand rejected under 35 USC §103(a) as being unpatentable over Minter et al. (WO 00/33063) in view of Parsons et al. (EP 0321736). Specifically, the Examiner asserts that Parsons et al. "teach a test capillary that incorporates a particulate material to enhance the change in flow rate." This rejection is respectfully traversed.

As discussed above, Minter et al. do not teach or suggest a testing device including a detection arrangement and a timer which, upon activation, sets a pre-determined time period for the test sample to reach the detection arrangement and wherein detection of the presence or absence of the liquid sample is made within the pre-determined time period, as recited in amended independent claim 1. The teachings of Parsons et al. do not overcome at least this deficiency of Minter et al.

Applicants thus submit that neither Minter et al. nor Parsons et al., taken either singly or in combination, teach or suggest the presently claimed invention and that this rejection of claims 13, 14 and 16 under 35 USC §103(a) may be properly withdrawn.

Claim 15 stands rejected under 35 USC §103(a) as being unpatentable over Minter et al. (WO 00/33063) in view of Parsons et al. (EP 0321736), and further in view of Alcock et al. (US 5,736,188). This rejection is respectfully traversed.

The teachings of Minter et al. and Parsons et al. are discussed above. Alcock et al. describe a printed fluid circuit device, in which a bibulous membrane is used as the base substrate and channels are produced by impregnating the material with an impervious material to constrain the fluid. The Examiner asserts that Alcock et al. teaches the use of silica or bentonite as an inert particulate material. However, Alcock et al. do not overcome the deficiencies of Minter et al. and Parsons et al. discussed above.

It is thus submitted that neither Minter et al., Parsons et al. nor Alcock et al. would have rendered the presently claimed invention obvious to one of skill in the art at the time the invention was made, and that this rejection of claim 15 under 35 USC §103(a) may be properly withdrawn.

Concluding Remarks

A Request for a Three Month Extension of Time, extending the deadline for responding to the Office Action to February 20, 2008, is submitted herewith.

Every effort has been made to put the application in condition for allowance. Early reconsideration and allowance is respectfully requested. Should the Examiner have any remaining concerns regarding the subject application, she is respectfully requested to telephone the undersigned at 206.382.1191.

Respectfully submitted,

By: Janet Sleath

Janet Sleath
Registration No. 37,007

Date: February 12, 2009

SPECKMAN LAW GROUP PLLC

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